

Briefing Paper
Biotech MCAN J-16-0036, 0037, 0038, 0039, 0040, 0041

PART I: BACKGROUND DATA

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Options Meeting Date: November 22, 2016

Dispo Meeting Date: November 28, 2016

A. CBI Claims: Submitter Identity, Chemical identity, Use, Recipient microorganism, Donor microorganism, Genetic construct, Exposure, Production volume, Process information.

B. Submitter: [REDACTED]

[REDACTED]

Table 1.

[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

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*The bold font indicates new modifications in this current MCAN whereas the regular font shows the changes that were also made in J

where:

[REDACTED]

C. Production volume

i) Maximum PV (Year 3): [REDACTED]

D. Use: [REDACTED]

PART II: Recommendation and Rationale

Not likely to present an unreasonable risk.

[REDACTED]

PART III: Introduction

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

PART IV: Risk Summary

There is low risk to human health associated with the production and use of the six intergeneric strains [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

A. Human Health Hazard

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

B. Ecological Hazard

There are low ecological hazard concerns for the recipient microorganism, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]